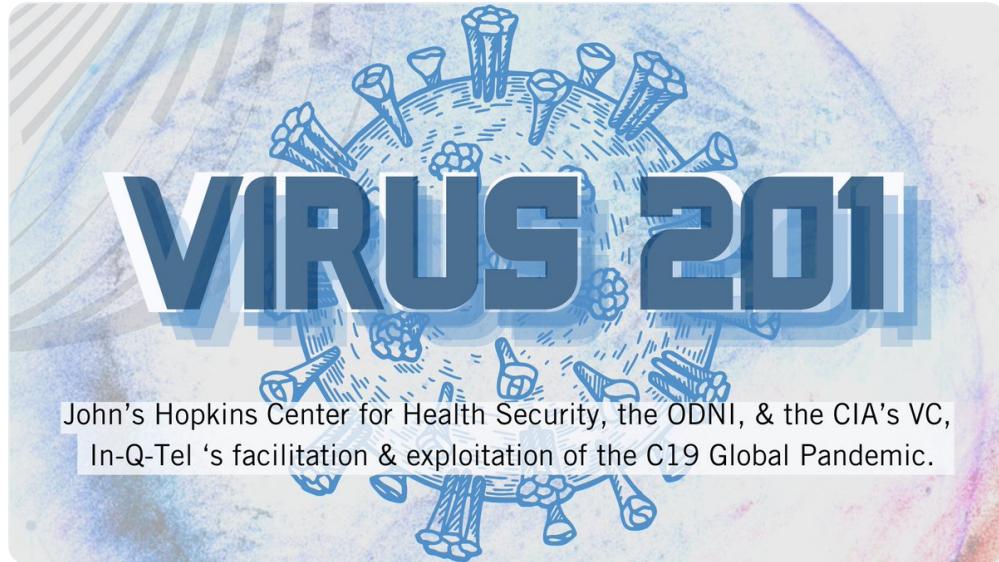




Destiny Rezendes @dezzie\_rezzie

Mar 6, 2024 • 19 tweets • [dezzie\\_rezzie/status/1765451927884628134](https://dezzie.rezzie/status/1765451927884628134)

1  The significant portion of the US Intelligence Community has admitted to believing that the C19 pandemic likely originated in the Wuhan Lab. What they failed to mention is how they strategically facilitated the emergence of C19 & then exploited the response.



2  Seven+ months ago I authored a thread showing the CIA's tech arm, In-Q-Tel [IQT] held a round-table tabletop exercise [TTX] in December of 2019. The TTX foreshadowed a global epidemic that would use machine learning on 5G to manage the "specturm of illness."

b.next

ROUNDABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

December 2019

**Introduction**

The capabilities required to manage a large-scale epidemic are multifaceted, complex and range across a number of critical domains – the ability to detect and recognize the presence of disease in the community; the capacity to design, manufacture and deliver life-saving medical countermeasures, including therapeutics and vaccine; and the process by which healthcare services can be delivered to the population-in-need in a scalable fashion that maintains the highest possible standard of care.

**Background**

In-Q-Tel/B.Next convened a Roundtable meeting, held on December 5, 2019 in Arlington, VA to explore the role digital health technologies can play in allowing the U.S. to respond to large infectious disease outbreaks. The meeting participated in by experts drawn from several U.S. Governmental, non-Governmental, academic, private-sector technology companies and members of the In-Q-Tel and B.Next team. The discussion took place over a single day. There were two invited presentations, and the meeting was conducted on a no-attribution basis.

This Roundtable discussion was the first of a series of meetings which intend to explore how digital health technologies might be applied to epidemic management. This focus was expressed expressly on two topics: the role digital health technologies can play in allowing the U.S. population to practice self-isolation, and how such technologies might aid in preserving the delivery of medical services over the course of an extended outbreak period. Subsequent Roundtable discussions in this series will explore the potential of these technological platforms to help provide appropriate medical treatment in an austere environment where resources are scarce. We will also examine how digital health technologies might enable the collection, analysis and coordination of data in order to provide essential situational awareness, thereby facilitating the creation of a “learning healthcare system” in the midst of an epidemic crisis.

**Overview of Topic: Digital Health tools will be critical to managing epidemic events.**

The potential roles that digital health technologies might serve during an epidemic requires an understanding of the likely adoption rate, capabilities, and limitations of such technologies. The rationale for this approach is based upon three key points. The first is that healthcare service delivery is currently undergoing a fundamental shift toward the increasing adoption of digital health tools. Changes in the marketplace are forcing health care providers to meet the needs of an aging population, the need to reduce costs, and respond to demands for more efficient access to care. The second is that the platforms that support digital health tools – namely the adoption of the smartphone with its consumer facing applications, along with the extension of broadband internet connectivity – are widely available in the U.S. This facilitates the ability to exchange meaningful and timely health-related

All Rights Reserved, 2019, In-Q-Tel

1

**IQT**

**Destiny Rezendes**  @dezelle\_rezzie · Aug 22, 2023 Promote ...

1 Unbeknownst, a narrative shattering report had been sitting amongst my files for months. The report is so damning & so suspect it calls into question everything we've been told about the Pandemic. (links will be in a comment at the end) 

30 368 450 85K

**Destiny Rezendes**  @dezelle\_rezzie · Aug 22, 2023 ...

6 In-Q-Tel repeated the need for; track and trace technology, digitalized health care system, implementing “tel-health” over hospital trips, wearable sensors, at home testing, & even REFUSING patients who weren’t, “ill enough to warrant formal clinical care”

 **b.next**

**Key Takeaways**

The following are the key takeaways from the In-Q-Tel discussion:

- ① The ability to use individual communication platforms (SMS, text, voice, video and conversations thereof) to largely sustain epidemic event requires further exploration and refinement.
- ② Successful triage and delivery of medical services during a large-scale epidemic will be largely dependent upon the ability to quickly and accurately identify the most critical patient and disease decisions making.
- ③ Early detection of an epidemic and the ability to rapidly triage and treat individuals without access to and trust medical services during an epidemic is essential. These issues must be addressed in order to ensure the most vulnerable populations are not left behind.
- ④ Market and demographic factors are already driving the utilization of digital health tools in the health care space.
- ⑤ The U.S. government is unlikely to develop the technology required to support the full range of epidemic needs. The government will likely need to partner with the private sector and the private sector will need to demonstrate that they can provide these capabilities through incentives and funding designed for this purpose.

**Ability to use requires further exploration** (gap) is our knowledge base and understanding of the capacity for digital communication platforms to manage robust and sustained utilization of services over extended periods of time. This gap is further compounded by the need to support the increasing complexity of the communication services utilized (data/multimodal/microservices). However, further exploration is required to determine the most effective way to support the epidemic event. What are the communication best practices for current systems to support, in what medium, and over what bandwidths? What are the best practices for the most effective use of the communication bandwidths, was described as “fragile” and the wireless spectrum question was referred to as a “fragile” asset. The communication bandwidths are described as “fragile” because they are a dimension of the overall network system. In addition to the communication network system

3  Now I've found the second In-Q-Tel TTX document that's from November 5, 2019 titled, Delivering the Biorevolution. The document focuses on which vaccine platforms they would like to see in response to an emerging disease pandemic, 2 months before C19!



## Delivering the biorevolution: a BNext Workshop on cellular delivery technologies

November 5, 2019

Dylan George<sup>1</sup>, Tara O'Toole<sup>2</sup>, BNext et al

**Summary:** This workshop was motivated by BNext's interest in technologies that facilitate timely response to infectious disease outbreaks through the rapid design and manufacture of vaccines against newly emergent pathogens.

A compelling technology for rapid response to an ongoing outbreak is nucleic acid-based vaccines. Nucleic acid-based vaccines are attractive for rapid response because, in theory, DNA or RNA antigens that provoke a protective immune response could be quickly and inexpensively designed, manufactured, and used speedily in the clinic. Big pharma and biotech companies are interested in advancing nucleic acid-based vaccines. Several candidates are in clinical trials, though no nucleic acid-based vaccines have achieved FDA approval. Among the hurdles associated with DNA or RNA-based vaccines are the following:

*All Available Cellular Delivery Technologies Have Limitations* - Major techniques to deliver the nucleic acid "payload" inside cells have been demonstrated - including electroporation, viral vectors and a variety of lipid nanocarriers - but all are problematic. Electroporation is suitable only for laboratory settings and not feasible in a mass casualty setting. Viral vectors carry the risk of unintentional immune reactions, and the virus carrier can only deliver certain types of payloads. Lipid nanocarriers are arguably the most advanced modality and are the delivery vehicle used in seven of eight ongoing RNA vaccine trials and in gene therapy trials. But they too are disadvantaged by the relatively "fragile" supply chain that is being used primarily for other products.

*Manufacturing viruses and lipids is itself a hurdle to be overcome*, especially if vaccine were needed in large quantities. For example, the supply chain capacity for GMP-grade lipids is limited, and currently being stretched by demand for the second-generation Shingles vaccine.

*Similarly, manufacture of GMP-grade nucleic acid at scale is not currently possible at speed and would probably require 12 months. Making DNA in the U.S. Government's Advanced Development Manufacturing Facilities may make this possible in 6 months.* Several biotech companies are working hard to improve de novo DNA synthesis, but we are not yet able to do this at the required scale and time frame. DARPA is starting a program to develop novel approaches for DNA manufacturing at scale too.

*Regulatory approval of novel cellular delivery methods* requires a time-consuming and costly investment of resources, a fact that creates a rational disincentive to innovate. Nonetheless, successful and safe cellular delivery is a central feature of many of the most promising new drugs, including gene therapies. The commercial stakes involved in these new approaches will likely advance the science of cellular delivery, hopefully to the benefit of nucleic acid-based vaccines.

*Conclusions:* Advances in delivery modalities other than the current mainstays – existing viral vectors, lipid nanocarriers – should be supported. Supporting alternative DNA synthesis technologies and nimble, efficient biomanufacturing capabilities should be a priority.

<sup>1</sup> Vice President, BNext, IQT

<sup>2</sup> Executive Vice President, BNext Director, IQT



technologies. Viral vectors and lipid nanocarriers are the delivery modalities that are furthest along in clinical trials for gene therapies (8) and mRNA vaccines (6); however, alternative delivery technologies – commensal viral vectors, polymer nanocarriers – need to be supported and tested as well.

**Manufacturing at scale:** Even when a vaccine that has been designed and tested in animal studies is available, manufacturing it at scale is challenging, especially for an ongoing outbreak that requires vaccine to be delivered quickly. Biotechnology companies typically lack resources to push vaccine development beyond preclinical work and early clinical trials. Late stage clinical trials and constructing unique manufacturing facilities drive the high costs associated with vaccine development. There are few major manufacturers<sup>8</sup> with the needed expertise working on vaccines (2), and they traditionally have developed bespoke manufacturing capabilities which constrain the speed and ability to pivot to novel threats.

The limits of current manufacturing have been a major motivation for developing nucleic acid vaccines which can be developed and produced at scale much more quickly than traditional approaches. One participant noted that while nucleic acid vaccines are promising, manufacturing quality nucleic acids at the scale needed for a mass outbreak have not been completely figured out (9) and likely will be deficient because manufacturing clinical GMP DNA can take anywhere from six to twelve months. Also, a participant highlighted that gene and cell therapies using delivery technologies will not require the same scale of manufacturing as would mRNA vaccines especially during surges of an ongoing outbreak. So, relying on commercial markets to develop the needed capacity may not yield the quantity of material demanded by a pandemic scenario. New synthetic biology approaches to manufacture DNA enzymatically instead of chemically potentially could be a means of addressing the manufacturing shortfall of clinical GMP DNA. Exploration of the potentials and deficiencies in nucleic acid synthesis are needed. Companies developing enzymatic approaches of DNA synthesis are exciting and warrant further attention as do companies developing novel, nimble, and efficient biomanufacturing capabilities.

DARPA



**Background:** Advances in synthetic biology are driving the creation of innovative therapies and vaccines that could transform rapid response capabilities for pandemics. These technologies – gene therapies, cell therapies, oncological immunotherapies, nucleic acid vaccines – require delivery of modified RNA or DNA to targeted cells to program those cells in order to have the desired clinical effect has significant technical challenges. On August 21, 2019, BNext convened a workshop of subject matter experts from industry, academia, and U.S. government agencies (Amy Jenkins – Program Manager DARPA, Mark Feinberg – CEO IAVI, Keith Wells – biomanufacturing consultant) to explore potential approaches to successful intracellular delivery technologies for vaccines which could be rapidly designed and quickly manufactured at a large scale. This paper reports on the workshop findings. The workshop was convened by B.Next, a division of IQT Labs, the research venture of In-Q-Tel (IQT).

**Vaccines are critical tools for countering infectious disease outbreaks:** Outbreaks of infectious diseases are an increasingly common, devastating feature of modern-day life which threaten lives and livelihoods. Modern patterns of trade, travel, commercial development drive such outbreaks. These outbreaks are fought by brave front-line clinicians and public health professionals armed with outdated data technologies, insufficient resources, and typically without effective vaccines or drugs. More often than not they fight outbreaks with 20<sup>th</sup> century tools. We need 21<sup>st</sup> century solutions to confront these 21<sup>st</sup> century health security challenges. At IQT we are actively pursuing technologies that provide the capabilities needed to respond to novel emerging infectious disease outbreaks.

Vaccines are the single most effective medical capability for countering infectious diseases (1), but vaccine development typically requires 15–20 years and approximately a billion dollars (2). The current process and enabling tools to discover, design, manufacture, and test a new vaccine are not well suited for rapid response. As a result of this long, expensive development process, vaccines historically have been unavailable to counter outbreaks of newly emergent disease (e.g., SARS 2003; Ebola 2014; Zika 2016).

4. Of viral vectors, lipid nanocarriers, GMP DNA, & mRNA the one most praised was mRNA.

Reasoning for this was, "RNA-based vaccines can be manufactured cell-free, which reduces complications associated with maintaining GMP cell lines..."



One workshop participant told the group about how the lack of a deployable vaccine allowed the Ebola outbreak of 2014-2016 in West Africa to rampage across Sierra Leone, Liberia and Guinea killing over 11,000 people and significantly destabilizing the region. At the time, no licensed vaccine or therapeutic was available, but several candidate Ebola vaccines had already gone through years of early stage development. Merck Vaccines was willing and able to step into the breach to advance a candidate through later stage development. With support from the USG and others, Merck, at considerable expense, licensed a candidate vaccine, contracted manufacturing capabilities, and began the process of testing the vaccine in hopes of providing life-saving vaccines to people in the region. Merck was able to shorten the development timeline from years to months. Fortunately the outbreak ended before this vaccine could be manufactured and deployed at scale. So, in the end, the vaccine did not significantly contribute to stopping that specific outbreak.

Despite the example of Merck Vaccines and other initiatives<sup>3</sup>, participants agreed that we continue to battle novel pathogen outbreaks without effective vaccines (3). Because time is critical during an outbreak, current methods of developing vaccines are not sufficient and technologies that can be designed and manufactured quickly will have more impact. Technologies that enable the discovery, manufacture, development, and use of vaccines in timeframes that would significantly counter an ongoing outbreak remain critically important. Promoting and developing vaccine technologies that enable rapid design and scaled-up manufacture has been a focus of some DARPA programs (e.g., Adept, P3). B.Next also continues to seek technologies that would enable vaccine design and manufacture in timeframes that would be applicable to stopping an epidemic.

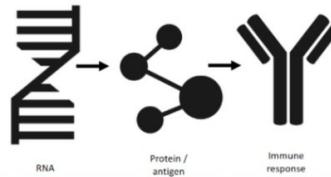
**Nucleic acid-based vaccines are promising technologies:** Nucleic acid vaccines, which deliver DNA or mRNA to generate an antigen, are particularly promising vaccine technologies for rapid outbreak response because, at least in principle, they can be rapidly developed and inexpensively manufactured (4).

mRNA is the intermediate molecule that enables the expression of a gene into a protein. It is the molecule that tells a cell what proteins to build. The idea behind mRNA vaccines is to design and use an mRNA that would tell the body's cells to generate a particular type of protein, an antigen, that will elicit a protective immune response for a specific disease (Figure 1). In short, nucleic acid vaccines biologically "program" a person at the cellular level to generate immunological protection. This programming should work as long as you are able to deliver the right information, that is the right mRNA, to the right cells in a body.

<sup>3</sup> See efforts by the Coalition for Epidemic Preparedness Innovation, <https://cepi.net/>

© 2019 IQT Labs, LLC

2



**Figure 1.** mRNA vaccines program cells to generate immune responses. mRNA vaccines accomplish immune responses by inserting an RNA molecule into cells to program the cellular production of a protective response in the body. The RNA molecule once in the cell is translated to a protein molecule. The protein, or rather antigen, elicits an immune response – generates antibodies or other mechanisms – that provides protection from the pathogen.

An advantage to mRNA vaccines is that RNA can be designed and, in theory, synthesized quickly using standardized processes. Traditional vaccine manufacturing is bespoke and typically requires a unique and expensive manufacturing facility for each vaccine, whereas with RNA production one manufacturing facility could be used for multiple vaccines because you are using a standardized system for RNA synthesis. Also, RNA-based vaccines can be manufactured cell-free, which reduces complications associated with maintaining GMP cell lines (5). Development of a mRNA vaccine can go from genetic sequence to mass production in three months, whereas traditional approaches would take many months to years to produce a new vaccine at scale. Despite such promise, however, no nucleic acid vaccines have yet been approved by the FDA, although several candidate vaccines have progressed to phase 1, 2 clinical trials (6).

Several participants were cautiously hopeful that mRNA vaccines could provide capabilities to address the challenges of rapid vaccine development, but the clinical trials still need to demonstrate candidate mRNA vaccines are safe and

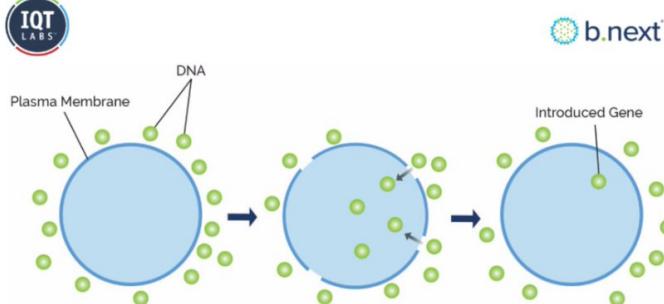
**Intracellular delivery: a vital component for effective vaccines:** A major challenge with nucleic acid vaccines is getting the genetic payload to the right place in the body so one's immune system can generate protection. The safe and effective delivery of genetic payloads within humans has been a focus for decades (7), (8).

Intracellular delivery includes not just the process of getting materials through cellular membranes, but also entails protecting payloads from degradation processes, and releasing payloads into a cell in a reliable way (3). Intracellular delivery is a linchpin for a range of therapeutic applications beyond vaccines, including gene-editing technologies. Participants noted that several Phase I trials of nucleic acid vaccines using novel delivery technologies are underway (4), (8), (9).

Participants discussed the three main delivery modalities for vaccines: electroporation, viral vectors, and lipid nanocarriers.

**Electroporation** is the process of applying an electrical field to a cell such that cellular membranes become transiently permeable, molecular cargo moves across the membrane, the cargo can be inserted into the cell, and the membrane is resealed (Figure 2). Electroporation has been used in microbiology since the 1970s and is widely used in basic and biomedical research. But there are limitations to its use outside a lab or in a mass administration situation.

The process can be highly efficient, but it is expensive and can create cell death if the electrical fields cause a permanent destabilization of a cell membrane or components. Electroporation can cause pain and muscle contractions which makes it less than appealing for treatment adherence if more than one dose is required. Most importantly, electroporation requires equipment to establish the electrical field and the portability of this equipment limits how widely it could be used outside of a clinic or laboratory setting. The value of electroporation is most apparent for *in vitro* and *ex vivo* investigations and applications, and not necessarily *in vivo* delivery.



**Figure 2.** Electroporation is the process of applying a temporary electrical field to a cell. The electrical pulse causes transient pores to develop in the cell membrane. Material can be inserted into cells while pores remain open.<sup>4</sup>

**Viral vectors** are another intracellular delivery modality for therapeutics and vaccines. Viruses have been honed over evolutionary time to infect cells with genetic payloads. Simplistically, one can think of viruses as molecular machines with two functional components – the container and the cargo. Viral vectors use the natural infection machinery – the container – of a virus but with modified genetic material – the cargo – that is to be inserted into a target cell (Figure 3). Viral vectors have been used for decades and in many clinical trials (10), and have been used in gene therapies approved by the FDA<sup>5</sup>. Notably the recent recombinant vesicular stomatitis virus Ebola vaccine (11) and recent high profile gene therapies (12) use this approach.

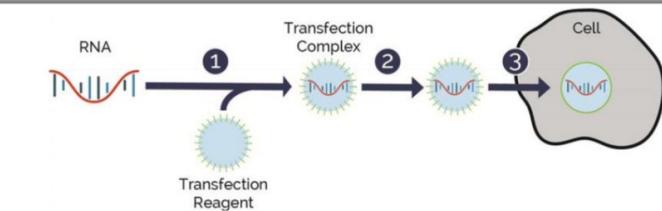
5 🎉 "Development of a mRNA vaccine can go from genetic sequence to mass production in three months, whereas traditional approaches would take many months to years to produce a new vaccine at scale."

⚠️ Their top concern was ease & speed-not effectiveness or safety. 🚫

immune responses to particular viral vectors. If this happens then the continued use of those vectors will not be possible in those individuals which will limit the therapeutics and vaccines that are in those vectors. Viral vectors are also limited by challenges in manufacturing large quantities of virus, the size of payloads, and by their ability to target many cell types. If the viral vector cannot infect certain types of cells, then we will not be able to program those cells with the genetic payloads. Finding viral vectors that can target specific cells will be an ongoing effort. So, researchers are actively searching for alternative viral vector systems to counter these limitations<sup>6</sup>.

**Lipid Nanocarriers** - Delivering nucleic acids or proteins cargo into cells can be achieved by using chemical reagents to construct delivery vehicles that have different properties. Many alternative cell delivery approaches such as lipid nanocarriers, polymer nanocarriers, and other nanomaterials have been explored to bypass the limitations of viral vectors (13). Lipid nanocarriers are the most advanced of these technologies for nucleic acid delivery (8), are currently being used in the majority of current clinical trials on mRNA vaccines (6), and were used in the first RNAi drug ("Patisiran"), approved by the FDA in August 2018. A recent review of mRNA clinical trials and delivery modalities found that seven of the eight of the ongoing clinical trials on mRNA vaccines are using lipid nanoparticles as their intracellular delivery modality (6).

Carrier systems based on chemical reagents can be limited by the features of the cargo (e.g., size, chemical properties, unpackaging abilities) and the target cell types. As with viral vectors, getting into some cell types is easier than others depending on cell receptors, surface interactions, and internal cellular processing pathways. For example, immortalized cell lines can be easily transfected, whereas blood and neurological cells pose difficulties (8). Because lipid nanocarriers have been easier to make relative to viral vectors, generate adjuvant effects, and do not generate unintended immunogenic responses, they have been broadly used to deliver nucleic acids in drug development. But see below for the challenges associated with "fragile" supply chains associated with lipid nanocarriers.



**Figure 4: Getting programmed RNA into cells – the transfection process:** 1) A chemical reagent is combined with a nucleic acid making a chemical complex of the two entities. 2) The combined reagent and nucleic acid interact with the cell surface. 3) Cells internalize the complex and the nucleic acid is ultimately released to the cell cytoplasm.<sup>7</sup>

#### Challenges and opportunities:

**Regulatory:** A major regulatory issue is the innovation disincentive within big pharma. An effective regulatory environment for medical countermeasures is necessary but can slow innovation. For biological pharmaceuticals such as vaccines, the manufacturing process itself contains much of the valuable intellectual property. To meet regulatory standards, the production process must reliably produce the same product which requires considerable investment of time and resources. Once a process has been validated and approved by a regulatory agency there is a rational disincentive to modify the process because major changes would require further regulatory approval and cost to provide the needed data. (14). Regulatory disincentives slow the pace of innovation for intracellular delivery

<sup>6</sup> For example, see the company Ring Therapeutics.

<sup>7</sup> Based on figure from <https://www.mirusbio.com>.



technologies. Viral vectors and lipid nanocarriers are the delivery modalities that are furthest along in clinical trials for gene therapies (8) and mRNA vaccines (6); however, alternative delivery technologies – commensal viral vectors, polymer nanocarriers – need to be supported and tested as well.

**Manufacturing at scale:** Even when a vaccine that has been designed and tested in animal studies is available, manufacturing it at scale is challenging, especially for an ongoing outbreak that requires vaccine to be delivered quickly. Biotechnology companies typically lack resources to push vaccine development beyond preclinical work and early clinical trials. Late stage clinical trials and constructing unique manufacturing facilities drive the high costs associated with vaccine development. There are few major manufacturers<sup>8</sup> with the needed expertise working on vaccines (2), and they traditionally have developed bespoke manufacturing capabilities which constrain the speed and ability to pivot to novel threats.

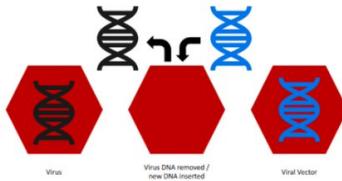
The limits of current manufacturing have been a major motivation for developing nucleic acid vaccines which can be developed and produced at scale much more quickly than traditional approaches. One participant noted that while nucleic acid vaccines are promising, manufacturing quality nucleic acids at the scale needed for a mass outbreak have not been completely figured out (9) and likely will be deficient because manufacturing clinical GMP DNA can take anywhere from six to twelve months. Also, a participant highlighted that gene and cell therapies using delivery technologies will not require the same scale of manufacturing as would mRNA vaccines especially during surges of an ongoing outbreak. So, relying on commercial markets to develop the needed capacity may not yield the quantity of material demanded by a pandemic scenario. New synthetic biology approaches to manufacture DNA enzymatically instead of chemically potentially could be a means of addressing the manufacturing shortfall of clinical GMP DNA. Exploration of the potentials and deficiencies in nucleic acid synthesis are needed. Companies developing enzymatic approaches of DNA synthesis are exciting and warrant further attention as do companies developing novel, nimble, and efficient biomanufacturing capabilities.

**Supply chain constraints:** One participant reminded the group that as we think about new technologies for outbreak response, we need to think about manufacturing capability and the supply chain of constituent materials, particularly we need to consider “fragile” supply chains. Constraints in manufacturing supply chains may limit the development and use of nucleic acid vaccines and delivery technologies. Competing markets for component materials have caused shortages for manufacturing clinical GMP lipid products. A good example is the vaccine called Shingrix<sup>9</sup>. This vaccine prevents shingles (herpes zoster) and is made up of the antigen, glycoprotein E, and an adjuvant, AS01B. People generally lose capacity to generate an immune response as they age, and the vaccine was developed specifically to generate immune responses in older people. The adjuvant is critical to generating the immune response, and is liposome based. The market for Shingrix is large. So, GlaxoSmithKline, the manufacturer, has acquired a major portion of the lipid supply to maintain Shingrix production which has disrupted the lipid supply chain for other uses. It remains unclear if these lipid supply chain challenges will persist or manufacturing capabilities will eventually compensate. But, in the short run the lack of raw materials will delimit manufacturing capabilities for other lipid-based products such as delivery technologies.

**Conclusions:** The workshop found that there were persistent scientific, regulatory, manufacturing, and supply chain challenges for advancing nucleic acid vaccines and delivery technologies. Significant research is ongoing in novel delivery modalities and it will be exciting to see those results in the next few years. The interface of regulation and innovation will continue to provide safety assurances yet will disincentivize the adoption of innovation in biomanufacturing. Supply chains for component materials will be a fluid environment and should be monitored because they could significantly limit capacity during an outbreak scenario. Advances in delivery modalities other than the current mainstays – existing viral vectors, lipid nanocarriers - should be supported. Supporting alternative DNA synthesis technologies and nimble, efficient biomanufacturing capabilities should be a priority.

<sup>8</sup> For example, GlaxoSmithKline, Merck, Pfizer, Sanofi Pasteur  
<sup>9</sup> <https://www.shingrix.com/index.html>

6. An author of the TTX was Tara O'Toole who not only is VP at IQT, & laboratories, but she is also the DoDs premier doomsday TTX writers and a senior advisor for Johns Hopkins Center for Health Security [JHCHS] [B.Next](#)



**Figure 3.** Viral vectors are made by using existing viruses, removing the virus DNA, and inserting new DNA that is to be used to program a cell for research or biomedical purposes.

However, this technology has limitations. The most well-known shortcoming of viral vectors has been unintentional immune reactions in patients. In 1999, a teenager suffering from a rare genetic disorder tragically died from an immune reaction to a viral vector used during a gene therapy trial. This tragedy set back the field of gene therapy for a decade. Even if we are able to avoid similar acute tragedies in the future, some people will produce

<sup>4</sup> Based on a figure from <https://courses.lumenlearning.com/microbiology/chapter/microbes-and-the-tools-of-genetic-engineering/>

<sup>5</sup> Zolgensma is a gene therapy for treating pediatric patients with spinal muscular atrophy, and was recently approved by the FDA in May 2019. Zolgensma uses an adeno-associated virus vector for intracellular delivery of the gene therapy.

**IQT LABS** **b.next**

**Bibliography**

1. Plotkin, Stanley, et al. *Plotkin's Vaccines*. s.l. : Elsevier, 2017.
2. Vaccines and global health: In search of a sustainable model for vaccine development and delivery. Rappuoli, Rino, Black, Steven and Bloom, David. s.l. : Science Translational Medicine, 2019, Vol. 11.
3. Influenza vaccine development challenges and opportunities. USG. s.l. : PCAST, 2012 [?].
4. mRNA vaccines - a new era in vaccinology. Pardi, Norbert, et al. s.l. : Nature Reviews Drug Discovery, 2018.
5. Self-amplifying RNA vaccines give equivalent protection against influenza to mRNA vaccines but at much lower doses. Vogel, Annette, et al. 2, s.l. : Molecular Therapy, 2018, Vol. 26.
6. mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases. Maruggi, Giulietta, et al. 4, s.l. : Molecular Therapy, 2019, Vol. 27.
7. LeMieux, Julianne. Going Viral: The Next Generation of AAV Vectors. *Genetic Engineering and Biotechnology News*. <https://www.genengnews.com/insights/going-viral-the-next-generation-of-aav-vectors/>, 2019.
8. *In vitro and ex vivo strategies for intracellular delivery*. Stewart, Martin, et al. 2016, Nature Biotechnology.
9. Jenkins, Amy - personal communication.
10. Adenovirus Vectors for Gene Therapy, Vaccination, and Cancer Gene Therapy. Wold, William and Toth, Karoly. 6, s.l. : Current Gene Therapy, 2013, Vol. 13.
11. A recombinant vesicular stomatitis virus Ebola vaccine. Regules, JA and al. et. 4, s.l. : New England Journal of Medicine, 2017, Vol. 376.
12. State-of-the-art gene-based therapies: the road ahead. Kay, M.A. s.l. : Nature Reviews Genetics, 2011, Vol. 12.
13. Non-viral vectors for gene-based therapy. Yin, Hao, et al. s.l. : Nature Reviews Genetics, 2014, Vol. 15.
14. Plotkin, Stanley, Mahmoud, Adel and Farrar, Jeremy. Establishing a Global Vaccine-Development Fund. *New England Journal of Medicine*. 2015, Vol. 373, 4.

[https://www.iqt.org/wp-content/uploads/2022/12/drugdeliveryFindings\\_nov5.pdf](https://www.iqt.org/wp-content/uploads/2022/12/drugdeliveryFindings_nov5.pdf)

7 As a re-cap on the first IQT TTX which was 1 month before the pandemic and among its listed authors were: CDC, DOD, ASPR, Luciano Borio[IQT/FDA], O'Toole, Robert Walker [ARMY] & Event 201s Top script writer/senior analyst Eric Toner of JHCHS.



**Participant List:**

Dr. Rima Abdel-Massih	ID Connect, University of Pittsburgh Medical Center Enterprises
Mr. JJ. Ben-Joseph	IQT/B.Next, Technical Staff
Dr. Luciana Borio	IQT/B.Next, Technical Staff
Mr. Joseph Buccina	IQT/B.Next, Director of IC Support and B.Next Operations
Dr. Brendan Carr	Director, Emergency Care Coordination Center, HHS/ASPR
Mr. Eugene Chiu	IQT/B.Next, Investment Team Member
Mr. Julius Dodson	IQT/B.Next, Intern
Dr. Dylan George	IQT/B.Next, Technical Staff
Dr. M. Kathleen Glynn	Deputy Director, Center for Preparedness and Response, CDC
Dr. Dan Hanfling	IQT/B.Next, Technical Staff
Dr. Andrew Le	CEO, Buoy Health
Mr. Eric Mair	IQT, Technical Staff
Dr. Carrie McNeil (phone)	Sandia National Laboratories, Technical Staff
Mr. Michael Meyer	CEO, Quiq
Mr. W.B. "Mitch" Mitchell	Group Vice President, Government Solutions, American Well
Mr. Isaac Myaou	IQT, Technical Staff
Dr. Kevin O'Connell	IQT, Technical Staff
Dr. Tara O'Toole	IQT/B.Next, Executive Vice President
Dr. Anita Patel (phone)	Senior Advisor, Influenza Coordination Unit, CDC
Dr. Stephanie Rogers	IQT/B.Next, VP, Lab Operations and Bioinformatics
Mr. Ran Shaul	Co-founder, KHealth
Dr. Eric Toner	Senior Scholar, Johns Hopkins Center for Health Security
Mr. James Tyson	Branch Chief, Situational Awareness Office, CDC
Dr. Robert Walker	Office of the Army Surgeon General
Mr. Grant Whiting (phone)	IQT/B.Next, Investment Team Member
Dr. David Whittaker	CMO, DHA Innovation Group, Office of the Secretary of Defense

ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING  
LARGE-SCALE EPIDEMICS

December 2019

**Introduction**

The capabilities required to manage a large-scale epidemic are multifaceted, complex and range across a number of critical domains – the ability to detect and recognize the presence of disease in the community; the capacity to design, manufacture and deliver life-saving medical countermeasures, including therapeutics and vaccine; and the process by which healthcare services can be delivered to the population-in-need in a scalable fashion that maintains the highest possible standard of care.

**Background**

In-Q-Tel/B.Next convened a Roundtable meeting, held on December 5, 2019 in Arlington, VA to explore the role digital health technologies can play to support the response to large infectious disease outbreaks. Roundtable participants included experts drawn from several United States (U.S.) Government agencies, academia, private-sector technology companies and members of the In-Q-Tel and B.Next team. The discussion took place over a single day. There were two invited presentations, and the meeting was conducted on a not-for-attribution basis.

This Roundtable discussion was the first of a series of meetings which intend to explore how digital health technologies might be applied to epidemic management. This meeting was focused expressly on two broad themes – the role enabling technologies can play in allowing the population to initiate self-triage, and how such technologies might aid in preserving the integrity of hospital services over the course of an extended outbreak event. Subsequent Roundtable discussions in this series will explore the potential of these technological platforms to help provide appropriate medical treatment in an austere environment where resources are scarce. We will also examine how digital health technologies might enable the collection, analysis and coordination of data in order to provide essential situational awareness, thereby facilitating the creation of a “learning healthcare system” in the midst of an epidemic crisis.

**Overview of Topic:** *Digital Health tools will be critical to managing epidemic events.*

The potential roles that digital health technologies might serve during an epidemic requires an understanding of the likely adoption rate, capabilities, and limitations of such technologies. The rationale for this approach is based upon three key points. The first is that healthcare service delivery is currently undergoing a fundamental shift toward the increasing adoption of digital health tools. Changes in the marketplace are driving rapid changes in healthcare service delivery. These forces include the need to reduce costs and respond to patient demands for more efficient access to care. The second is that the platforms that support digital health tools – namely the adoption of the smartphone with its consumer facing applications, along with the extension of broadband internet connectivity – are widely available in the U.S. This facilitates the ability to exchange meaningful and timely health-related

1

All Rights Reserved, 2019, In-Q-Tel

8 Where this all become extremely concerning is within the context. The CIAs In-Q-Tel massively funded Palantir & Metabiota additionally the President of IQT, Chris Darby sits on the Board for the C19 maker for Moderna, National Resilience.





**Luciana Borio:** Former FDA Chief Scientist, VP of the CIA's In-Q-Tel, CFR, COVAX, President's Transition COVID-19 Advisory Board, Arch Ventures, Inspired the creation of Moderna's C19 Manufacturer, National Resilience Inc, Johns Hopkins Alumni & Advisor, Partner w. BMGF



**Robert Nelson:** Founder & Board of Directors for National Resilience [Moderna's C19 manufacturer], Founder of Arch Ventures, CFR



**Chris Darby:** Board of Directors for National Resilience [Moderna's C19 manufacturer], President of the CIA's In-Q-Tel.



**Tara O'Toole:** Senior Advisor at Johns Hopkins Center For Health Security [JHCHS], Pandemic exercise author: Crimson Contagion, Dark Winter, B.Next Lab, VP In-Q-Tel, Under Sec of Homeland Security for Science & Tech under Obama.



**Avril Haines:** Former CIA Director under Obama, Managing Director for President Biden's Transition Team, Event 201 Player, Johns Hopkins University Drop-out, current director for the ODNI, Georgetown Alum.



- HOW WE WORK
- PORTFOLIO**
- IQT LABS
- INSIGHTS & NEWS
- ABOUT



**Thetus**  
AI-ENABLED APPLICATIONS



**Palantir**  
AI-ENABLED APPLICATIONS



**Cassatt**  
AI-ENABLING PLATFORM



**Metabiota**  
AI-ENABLED APPLICATIONS, BIOTECHNOLOGY

Palantir [Joe Lonsdale Nathan Wolfe]: Lonsdale co-founded Palantir which the USG hired for the Operation Warp speed platform "Operation Tiberius" that was in charge of the delivery & tracking of every US dose of C19 Vaccine. Nathan Wolfe founder of Metabiota & Palantir have collaborated together on multiple projects over the past 10yrs. Lonsdale is on the Board for Resilience.

Metabiota {Hunter Biden/Nathan Wolfe}: Worked w/ EcoHealth Alliance in the years preceding the pandemic. In-Q-Tel began financing them in 2017. Hunter Biden became a majority stock holder in Metabiota in 2014. In In-Q-Tels 2019 IRS-990 Metabiota was listed under the top 5 contracts with In-Q-Tel at over \$1.3Million

In-Q-Tel    Metabiota    CIA    PALANTIR

9. To make matters worse, Resilience was founded by Robert Nelson[Board of Directors for Resilience] who credited Luciana Borio for inspiring the company's creation. Also Joe Lonsdale of Resilience co-founded Palantir which managed Operation Warp Speed [OWS] w/the DoD for C19.

## Board of Directors

## RESILIENCE



Robert Nelson  
Chairman and Founder, ARCH



Patrick K. Yang, PhD  
Vice Chairman, Former EVP Juniper Networks



Joe Lonsdale



Drew Oetting



Frances Arnold, PhD  
Nobel Prize Laureate, CalTech Professor



George Rabbitt  
President & CEO, Cytel Health



Michael E. Daniels, Jr.  
President, Purdue University, Former Governor of Indiana



Chris Kirby  
CEO, In-Q-Tel

## In-Q-Tel Metabiota CIA PALANTIR

Oetting is also the co-founder of 8VC, a venture capital firm that is one of the main investors in Resilience. 8VC's other co-founder is Joe Lonsdale and Oetting "started his career" as Lonsdale's chief of staff. Lonsdale is the co-founder, alongside Peter Thiel and Alex Karp, of Palantir, a CIA front company and intelligence contractor that is the successor to DARPA's controversial Total Information Awareness (TIA) mass surveillance and data-mining program. In addition, Oetting previously worked for Bill Gates' investment fund.

10 Now, remember that O'toole, Toner, & Borio are all JHCHS, which is who hosted Event 201. At Event 201 our current head of the ODNI & FORMER CIA DIRECTOR, Avril Haines [Johns Hopkins drop out] was an official player at the event & ODNI lead the investigation into the origins of the pandemic!

11 The JHCHS team were very busy because they had also done a paper for the Global Preparedness Monitoring Board [GPMB] Sept of 2019; predicting a respiratory pandemic-that might have been leaked from a lab. On the GPMB board for the paper? Dr. Anthony Fauci.



**GPMB**

In September of 2019, the GPMB commissioned a white paper with JHCHS titled "Preparedness for a High Impact Respiratory Pandemic"

The writers of this document also wrote the script for Event 201, less than one month later.

Founding Board Member for GPMB at the time of the paper's commissioning was NIAID Director Anthony Fauci.



GLOBAL PREPAREDNESS MONITORING BOARD

[Home](#) [About us](#) [News](#)

[Home / Reports / m / item](#)

**Preparedness for a High-Impact Respiratory Pathogen Pandemic**

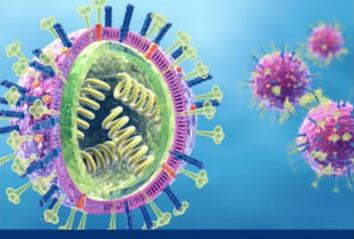
Johns Hopkins Center for Health Security

10 September 2019 | Publication

**The WHO + The World Bank created the Global Preparedness Monitoring Board in 2017**

**A World at Risk: GPMB 2019 Annual Report**





Johns Hopkins Center for Health Security

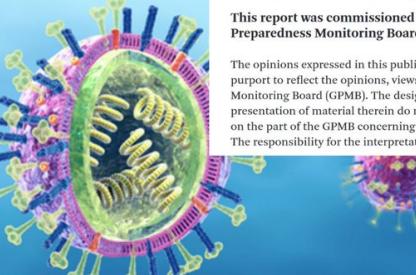
**Preparedness for a High-Impact Respiratory Pathogen Pandemic**

September 2019




This report was commissioned by and prepared for the Global Preparedness Monitoring Board.

The opinions expressed in this publication are those of the authors. They do not purport to reflect the opinions, views or recommendations of the Global Preparedness Monitoring Board (GPMB). The designations employed in this publication and the presentation of material therein do not imply the expression of any opinion whatsoever on the part of the GPMB concerning the legal status of any country, area or territory. The responsibility for the interpretation and use of this publication lies with the reader.



Johns Hopkins Center for Health Security

**Preparedness for a High-Impact Respiratory Pathogen Pandemic**

September 2019




**Dr Anthony S. Fauci**



Director, National Institute of Allergy and Infectious Diseases, USA

**Biography**

Anthony S. Fauci, M.D., is director of the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health, where he oversees an extensive research portfolio focused on infectious and immune-mediated diseases. He serves as one of the key advisors to the White House on COVID-19, with the U.S. Health Services on global HIV/AIDS issues, and on initiatives to bolster medical and public-health preparedness against emerging infectious disease threats. He is the winner of numerous prestigious awards including the Presidential Medal of Freedom, the National Medal of Science and the Lasker Award for Public Service.

## Background documents

10 SEPTEMBER 2019  
Advancing epidemics R&D to keep up with a changing world: Progress, challenges and...  
Welcome Trust

[Download](#)

[Read More](#)

10 September 2019  
The state of governance and coordination for health emergency preparedness and response

[Download](#)

[Read More](#)

10 September 2019  
Thematic paper on the status of country preparedness capacities

[Download](#)

[Read More](#)

**EVENT 201: HOSTED BY JOHNS HOPKINS CENTER FOR HEALTH SECURITY, THE WORLD ECONOMIC FORUM, THE BILL & MELINDA GATES FOUNDATION, OCTOBER 2019.**

**When/where**

Friday, October 18, 2019  
8 a.m. – 12 p.m. a.m.  
The Royal Theater  
New York, NY

**Audience**

An invitation-only audience of nearly 1,000 people:

Attended the exercise, and a cross-section of the event who attended for media coverage is invited.

**Exercise team**

Eric Toner, M.D., is the exercise team lead from the Johns Hopkins Center for Health Security. Jennifer M. Nuzzo, M.D., M.P.H., and Tom Frieden, M.D., M.P.H., are co-leads from the Johns Hopkins Center for Health Security. Jennifer Nuzzo is the Director of the Global Health Security Program, and Jennifer Frieden is the executive lead for the Bill and Melinda Gates Foundation.

Exercise team members: [Eric Toner](#), [M.D.](#); [Jennifer Nuzzo](#), [M.D., M.P.H.](#); [Tom Frieden](#), [M.D., M.P.H.](#); [Johns Hopkins Center for Health Security](#); [Jennifer Frieden](#), [Bill and Melinda Gates Foundation](#).

Executive team members: [Eric Toner](#), [M.D.](#); [Jennifer Nuzzo](#), [M.D., M.P.H.](#); [Tom Frieden](#), [M.D., M.P.H.](#); [Johns Hopkins Center for Health Security](#); [Jennifer Frieden](#), [Bill and Melinda Gates Foundation](#).

Exercise team was supported by funding from the [Gates Foundation Project](#).

CORE INITIATING TEAM  
Johns Hopkins Center for Health Security  
Jennifer B. Nuzzo, Senior Scholar  
Eric M. Toner, M.D., Senior Scholar  
Michael Steele, Analyst  
Thomas V. Inglesby, Director

CONTRIBUTORS  
Johns Hopkins Center for Health Security  
Amy S. Adalja, Senior Scholar  
Dawn M. Johnson, Senior Scholar  
Gigi K. Gronowski, Senior Scholar  
Diana M. Johnson, Senior Scholar  
Anindita Kholodenko, Analyst  
Kathleen M. Kelly, Senior Analyst  
Matthew L. Johnson, Senior Analyst  
Monica M. Spiesz, Senior Scholar  
Peter D. Sprecher, Senior Scholar  
Matthew Shearer, Senior Analyst  
Eric Tostee, Senior Scholar  
Matthew T. Tostee, Analyst  
Lance Wermuth, Analyst  
Christopher J. Wherry, Senior Scholar  
Matthew Watson, Senior Analyst

PRODUCTION TEAM  
Johns Hopkins Center for Health Security  
Julia C. Hwang, Project Manager  
Jackie Fox, Director of Publications  
Margaret Miller, Director of Communications

10 September 2019  
Preparedness for a high-impact  
Respiratory Pathogen Pandemic

[Download](#)

[Read More](#)

10 September 2019  
Pandemic Preparedness Financing: Status Update

[Download](#)

[Read More](#)

**THE EVENT 201 [OCT 2019] EXERCISE WAS WRITTEN BY 11 OF THE SAME AUTHORS AS THE GPMB'S "PREPAREDNESS FOR A HIGH-IMPACT RESPIRATORY PATHOGEN PANDEMIC REPORT**

12  And who created the GPMB [est 2017] The WHO & the World Bank. In September of 2019 the World Bank + GPMB [Fauci] released "PANDEMIC PREPAREDNESS FINANCING STATUS UPDATE" & to whom did they employ for their index data? Metabiota.

**WORLD BANK GROUP**  
Health, Nutrition & Population

## Pandemic Preparedness Financing STATUS UPDATE

September 2019

This report was commissioned by and prepared for the Global Preparedness Monitoring Board. The opinions expressed in this publication are those of the authors. They do not purport to reflect the opinions, views or recommendations of the Global Preparedness Monitoring Board. The designations employed in this publication and the presentation of material therein do not imply the expression of any opinion whatever on the part of the GPMB concerning the legal status of any country, area or territory. The responsibility for the interpretation and use of this publication lies with the reader.

**Background**

The Global Preparedness Monitoring Board intends to provide an authoritative, independent, comprehensive, inclusive overview of the state of global preparedness for health crises by issuing an annual report each year, commissioning special reports, and promoting global action. This first annual report will focus as its starting point updates on the status of implementation of recommendations that emerged after the West Africa Ebola Virus Disease outbreak in 2014–15 in several domains—country preparedness capacity, pandemic preparedness financing, governance and coordination of health crises, and research and development. The report will also assess the status of preparedness across all dimensions of all preparedness—as well as an examination of lessons learned from 2014–15 and current Ebola outbreaks, and risks associated with rapidly moving, high impact pandemics due to respiratory pathogens. It is envisaged that the status of preparedness will be updated each year with new data and information. The report will draw on materials that other monitoring or oversight bodies regularly produce (e.g., World Health Organization's Health Emergencies Program Independent Oversight and Advisory Committee reports), reports that the Global Preparedness Monitoring Board commissions to address topics that are not otherwise being reviewed, and other relevant published and unpublished reports.

This paper discusses pandemic preparedness financing and cuts across the dimensions of country capacity strengthening, governance and coordination, and research and development. The report is intended for a wide audience including policy-makers, government officials, financing agencies, and the public.

**Background**

The Global Preparedness Monitoring Board intends to provide an authoritative, independent, comprehensive, inclusive overview of the state of global preparedness for health crises by issuing an annual report each year, commissioning special reports, and promoting global action. This first annual report will focus as its starting point updates on the status of implementation of recommendations that emerged after the West Africa Ebola Virus Disease outbreak in 2014–15 in several domains—country preparedness capacity, pandemic preparedness financing, governance and coordination of health crises, and research and development. The report will also assess the status of preparedness across all dimensions of all preparedness—as well as an examination of lessons learned from 2014–15 and current Ebola outbreaks, and risks associated with rapidly moving, high impact pandemics due to respiratory pathogens. It is envisaged that the status of preparedness will be updated each year with new data and information. The report will draw on materials that other monitoring or oversight bodies regularly produce (e.g., World Health Organization's Health Emergencies Program Independent Oversight and Advisory Committee reports), reports that the Global Preparedness Monitoring Board commissions to address topics that are not otherwise being reviewed, and other relevant published and unpublished reports.

This paper discusses pandemic preparedness financing and cuts across the dimensions of country capacity strengthening, governance and coordination, and research and development. The report is intended for a wide audience including policy-makers, government officials, financing agencies, and the public.

**Archived Content**

WINTER 2021 Roundtable Report: Identifying Biodefense Intelligence as an Offensive Event

WINTER 2019 Digital Health Roundtable

FALL 2019 Drug Delivery Workshop

FALL 2019 Testimony of Tara O'Toole, MD, MPH

**Munich Re & In-Q-Tel Select Metabiota to Gain Deeper Insights into Epidemic Risk and Global Preparedness for Infectious Diseases**

AUG. 22, 2017

**Building an Effective Defense Against Biological Threats: The Technology Advantage**

MARCH 20, 2017

The United States faces significant and growing national security threats from increasingly frequent and disruptive natural epidemics of infection disease and potentially from covert biological weapons attacks on civilian populations. To address this issue, "Building an Effective Defense Against Biological Threats: The Technology Advantage" report, which adoption of existing and emerging biotechnologies, and use of digital communications and analytical tools, could greatly improve epidemic detection and management. The piece is authored by IQT Innovation Fellow Michael S. O'Leary, M.D., M.B.B.S.

13  Fast forward to post C19 emergence & we find that IQT released a 3rd round-table in 2021. In it they say, "The C19 pandemic has served as a "forcing function" & that "The design, testing & manufacture of effective mRNA vaccines w/in 1yr of the virus being sequenced by Operation Warp Speed "set a new normal."

**iqt** B.NEXT.

**IQT Roundtable: Capabilities Required for Pandemic Response – August 2021**

**Introduction**

On August 12, 2021, In-Q-Tel (IQT) convened a virtual Roundtable meeting to examine the technologies used to respond to the Covid-19 pandemic and other epidemics, to discuss what needed capabilities were missing from the Covid response, and how these critical needs might be addressed. Roundtable participants included experts drawn from several United States government (USG) agencies, academia, private-sector technology companies, and members of the IQT/B.NEXT network (see Roundtable Participants pg. 14). The meeting was conducted on a not-for-attribution basis.

For over two decades, increasingly frequent and consequential outbreaks of infectious disease have demonstrated that we are living in an “age of epidemics”. It is urgent that nations become more adept, individually and collectively, at controlling disease outbreaks. While improving global preparedness requires changes in national, institutional, and individual behaviors, many of the capabilities required to respond to lethal, fast-moving epidemics are technologies which can be realized through collaboration among governments, universities and private companies.

Our collective struggle against Covid-19 has demonstrated that technologies, ranging from dispensing devices to personal protective equipment and contact tracing apps, are essential to the task of operating pandemic. Yet, with a few exceptions, analyses of how technologies might enable critical pandemic management functions, and the strategies required to make such technologies widely available for this—or the next—pandemic, remain the exception, not the rule.

**Public policy / engagement goals:**

- Communicate advances in support of the above goals to the public on an ongoing basis to establish credibility between outbreaks
- Engage communities with proven expertise (such as Silicon Valley) to improve best practices in getting the public to adopt new technologies
- Recognize that behavioral and cultural changes, along with vaccines, are a line of defense ahead of protective equipment

All Rights Reserved, In-Q-Tel, 2021

All Rights Reserved, In-Q-Tel, 2021

**Effective Response to Future Pandemics Requires Imagination and Aggressive Efforts Now**

The COVID-19 pandemic has served as a “forcing function”, driving adoption of innovative technologies such as telemedicine, smart phone diagnostic applications, and the first large scale manufacturing use of mRNA vaccine technologies. But these technologies mostly existed before the pandemic began. During Covid, though vital, represented incremental technological progress rather than radical improvements.

The Covid-19 pandemic did not, for example, catalyze the use of technologies such as micro-drones, telemedicine, or sensors that might have allowed self-administration of vaccines without needles or syringes. Such delivery technologies might have increased vaccine uptake and relieved some of the burden on medical and public health systems. These technologies already exist commercially, but the small companies producing them found it challenging to gain attention or scale up during the crisis.

The design, testing and manufacture of effective mRNA vaccines within one year of the virus emerged as a success story. Such technologies might have allowed self-administration of vaccines without needles or syringes. Such delivery technologies might have increased vaccine uptake and relieved some of the burden on medical and public health systems. These technologies already exist commercially, but the small companies producing them found it challenging to gain attention or scale up during the crisis.

It remains unclear what will happen to the more than 100 Covid-19 vaccine candidates still completing clinical trials. Market forces alone are unlikely to promote novel vaccines beyond those which have already gained regulatory approval. Yet it is possible that some of these pipeline vaccines could prove essential in the next pandemic.

Still to come – and perhaps the most difficult goal of making and distributing enough vaccine for the world’s population in the present era of global trade and travel – a national approach to pandemic control is doomed to failure. Clearly, an enormous increase in the Covid vaccine manufacturing capacity is needed. How to do this efficiently and in a manner that enables governments and industry to mount rapid responses to emergent pathogens in this age of epidemics is an urgent priority.

Effective detection, management and resolution of infectious disease epidemics requires a societal-wide response. The Covid-19 pandemic should provoke a critical review of the authorities, processes and resources that were brought to bear against this ferocious virus which has done so much damage. But we should also consider how we might better use of technologies to save lives and halt disease transmission. If we remain reliant on conventional technologies, we will always be at a disadvantage to set the pace of adopting new technologies, we will miss the opportunities to create the capabilities we need to respond rapidly to coming outbreaks – and to quench them before they become pandemics.

All Rights Reserved, In-Q-Tel, 2021

**Roundtable – Participants**

**Ben Joseph** is a Data Scientist at IQT Labs who works in the confluence of biosecurity and artificial intelligence, advises startups, and contributes to technical projects. He has a computer science degree from Johns Hopkins and previously worked for the National Security Agency.

**Nathan Burleigh** is the B.Next Intern at IQT this summer, focusing on innovation systems and biosecurity strategies. After IQT, he will join Deloitte Consulting as a Strategy Analyst in the Government and Public Services Practice. He holds a Bachelor of Science in Foreign Service from Georgetown University with a concentration in biotechnology and global health.

**Jane Bigman, MPH** is a Senior Health Policy Advisor for the Senate Committee on Health, Education, Labor, and Pensions Majority Staff (Senator Murray, D-WA). She previously worked at the Centers for Disease Control and Prevention and at the Carter Center. She holds an MPH from Emory University and a B.A. in Psychology and Spanish from Agnes Scott College.

**Leticia Borio** is a senior fellow for global health at the Council on Foreign Relations (CFR) and a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies. She previously held positions on the National Security Council and as a Vice President at IQT.

**Joe Bucella** is a Director of Intelligence Community Support and B.Next Operations. He focuses on customer engagement, team operations, and bioinformatics. Before joining the B.Next team he was an IQT program manager, a public sector consultant, and a biosurveillance analyst at a startup.

**Eugene Chiu** is a Senior Partner on In-Q-Tel’s Investments Team, leading IQT’s investments in healthcare and life sciences ventures with IQT’s B.Next team. He has also been responsible for a number of IQT investments in the areas of quantum computing, advanced analytics, and artificial intelligence. Prior to IQT, Eugene co-founded and led business development, marketing, and financial operations at multiple early stage technology companies. Eugene earned his A.B. in Biochemical Sciences from Harvard College, Master’s in Health Sciences and Technology from MIT, and MBA from Harvard Business School.

**David H. Donabedian, Ph.D.** is a Venture Partner at Longwood Fund, Startup CEO of Longwood-founded ImmunoID, and was the founding CEO of Longwood-founded Axial Therapeutics, a biotechnology company focused on the gut-brain axis. Prior to joining Longwood, Dr. Donabedian held various leadership roles at biopharmaceutical companies including AbbVie (NASDAQ: ABBV) and GlaxoSmithKline (NYSE: GSK). Dr. Donabedian holds a B.A. in Chemistry from St. Anselm College, a Ph.D. in Polymer Chemistry from the University of Massachusetts Lowell, and an MBA from the University of North Carolina.

All Rights Reserved, In-Q-Tel, 2021

**Asha M. George, DrPH** (invited) is the Executive Director of the Bipartisan Commission on Biodefense. She served on the Biden-Harris Transition Team and as a subcommittee staff director and senior professional staff for the US House of Representatives Committee on Homeland Security. She is a public health and national security expert.

**Dylan George, Ph.D.** is a Vice President at Gingko Bioworks, where he is helping to develop improved biosensors, surveillance, analytics, and capabilities to better engineer organisms. Prior to Gingko, Dr. George was a Vice President at In-Q-Tel (IQT) and held various positions in the United States Federal government (DoD, HHS, OSTP) where he developed analytics, promoted authorities, coordinated budgets, and enabled policies for better pandemic response and preparedness readiness.

**Peter Haaland, Ph.D.** is a freelance applied scientist and inventor solving transdisciplinary problems by way of IARPA, DARPA, the USAF, early-stage VC, and diverse advisory activities in government and industry.

**Dan Hanfling, MD** is a Vice President on the Technical Staff at In-Q-Tel and a practicing emergency physician with expertise in operational emergency medicine. Prior to coming to In-Q-Tel he spent four years at HHS/ASPR, and before that led healthcare emergency management efforts for the Nova Health System (Falls Church, VA). He currently co-chairs the National Academy of Medicine’s Forum on Medical and Public Health Preparedness.

**Matthew Hepburn, MD** is the Director of COVID Vaccine Development for the HHS-DoD Countermeasures Acceleration Group (formerly known as Operation Warp Speed). Prior to this he served as the Joint Project Lead for Enabling Biotechnologies for the Joint Program Office for Chemical, Biological, Radiological and Nuclear Defense (DoD), was a Program Manager at DARPA (2013-2019), and served as the Director of Medical Preparedness on the White House National Security Staff (2010-2013).

**Amy Jenkins, Ph.D.** joined DARPA as a Program Manager in June 2019. Her interests include the development of platforms for combating infectious diseases, as well as novel manufacturing technologies to support rapid medical products. Prior to joining DARPA as a PM, Dr. Jenkins was a Senior Scientist at Gryphon Schaffer where she contributed to development of novel sensors to detect infectious disease threats within BTD. Prior to supporting DARPA, Dr. Jenkins studied the virulence factors of, and antibodies targeting, multi-drug resistant bacterial pathogens at MedImmune. She also served as a National Research Council Postdoctoral Fellow at the United States Army Medical Research Institute of Infectious Diseases where she studied virulence mechanisms of biodefense pathogens. She received her Doctor of Philosophy degree in Chemistry and Chemical Biology from Clarkson University and her Bachelor of Science in Chemistry and Biomedical Science from Clarkson University.

**Peter Kaderlik, MD** is the former Assistant Secretary for Preparedness and Response at the Department of Health and Human Services and a member of Senator Richard Burr’s (R-NC) staff.

All Rights Reserved, In-Q-Tel, 2021

14  The participants of this round table included: Georgetown [CIA prep school], CIA's IQT, Former CIA, Johns Hopkins Center for Health Security, BSL3 Universities: Wisconsin-Madison & UNC Chapel Hill, NARMU, ARMY, ASPR, MIT, Google, Clinton Foundation & DARPA...

He spent more than 20 years as a career officer and physician in the United States Air Force before retiring as a Lieutenant Colonel. Since leaving the military, he has been involved in the White House, the U.S. Senate, and the Department of Defense. He holds a Bachelor's degree from the United States Air Force Academy, Doctorate of Medicine and Master's of Tropical Medicine and Hygiene from the Uniformed Services University of the Health Sciences, and Master's in National Security Studies from Georgetown University.

**Kathryn Kosuda, PhD.** is co-founder and CEO at Vaxess Technologies, a life science company focused on improving the efficacy and accessibility of vaccines using MiMIX™, a novel stabilization and skin delivery platform. Kathryn holds a PhD in Physical Chemistry from Northwestern University, did her postdoctoral research in the Department of Chemistry & Chemical Biology at Harvard, and began her career in pharmaceutical R&D at Merck Research Laboratories.

**James Lawler, MD, MPH** is Executive Director for International Programs and Innovation for the Global Health Security Program at the University of Nebraska Medical Center. He is also an Adjunct Professor of Global Health and a Senior Fellow in the Defense Innovation Board's Nebraska Biostorming Unit. Before joining the UNMC team in November 2017, he served 21 years in the US Navy Medical Corps. Dr. Lawler's work has spanned a broad array of research, policy, and field activities related to emerging and high-consequence infectious diseases, medical and public health preparedness, pandemic and outbreak response, and global health. Dr. Lawler served in national policy positions in both the White House Homeland Security Council Biodefense Office and the National Security Council Resilience Directorate spanning two administrations.

**Jim** is a Summer Investment Associate at In-Q-Tel, focusing on the biotechnology, medical, and enterprise technology sectors. He is a fourth-year JD/MBA candidate at Harvard Business School and Harvard Law School, and holds a B.A. in Economics from Harvard College.

**W.B. "Mitch" Mitchell** currently serves as Group Vice President, Government Solutions with Anwell. Mitch is a senior strategy and management professional with over 25 years passionately building businesses in healthcare and information technology. He combines expertise in Military and Veteran's Health, Telemedicine, Federal Health Programs, Patient Engagement and Clinical Health Strategy Development. Before joining Anwell, Mitch led Government Solutions for Ciox Health and for 15 years prior, Mitch led teams across McKesson/RelyHealth and Change Healthcare, supporting complex commercial and federal health IT, HIE and patient engagement programs.

**Kevin O'Connell, PhD** is Vice President and Technical Lead for In-Q-Tel, the IAT technology practice focused on life sciences and the intersection of biotechnology, healthcare, and national security. Prior to joining IQT, he was a researcher and principal investigator with the U.S. Army Edgewood Chemical Biological Center for 10 years, where he focused on pathogen detection and from Harvard College.

**Sanjeev Patel, PhD** is the Director of BARDA's Division of Research, Innovation, and Ventures (DRIVE). Prior to DRIVE, he founded KidneyX and PreventionX at the Department of Homeland Security from 2009-14 and Assistant Secretary of Energy from 1993-97. She was a founding member and Director of the organization now known as the John Hopkins Center for Health Security and professor of medicine and public health for the previous decade.

**Tara O'Toole, MD, MPH** was Executive VP and Senior Fellow at IQT since 2014 and is now an IQT Sr. Fellow. She served as Under Secretary of Science and Technology at the Department of Homeland Security from 2009-14 and Assistant Secretary of Energy from 1993-97. She was a founding member and Director of the organization now known as the John Hopkins Center for Health Security and professor of medicine and public health for the previous decade.

**Sandee Patel, PhD** is the Director of BARDA's Division of Research, Innovation, and Ventures (DRIVE). Prior to DRIVE, he founded KidneyX and PreventionX at the Department of Homeland Security from 2009-14 and Assistant Secretary of Energy from 1993-97. She was a founding member and Director of the organization now known as the John Hopkins Center for Health Security and professor of medicine and public health for the previous decade.

**Martijn Basser** is a senior fellow and director of the Technology and National Security Program at the Center for a New American Security (CNAS). Prior to joining CNAS, he was an executive at an AI startup and a hedge fund. He is a former CIA officer.

**Lewis Robinson, MD, PhD** is the Chief Medical Officer of Morristown Medical Center (MMC) within the Atlantic Health System (AHS). Dr. Robinson is a critical care physician and the physician executive lead for the COVID-19 response at MMC, which was one of the early impacted referral hospitals. At the peak of the COVID-19 surge in the Spring 2020, MMC had 20 COVID-19 intensive care beds and 100 COVID-19 patients in the hospital. MMC has cared for nearly 3500 hospitalized persons with COVID-19 and AHS for nearly 8500 hospitalized patients. AHS has administered thousands of doses of monoclonal abs, hundreds of thousands of vaccination doses, enrolled 100s of patients in therapeutic trials and has implemented numerous testing platforms for COVID-19/SARS-CoV-2.

**Patrick Rose, PhD** is the Program Manager for the Department of Defense Biomedical Manufacturing Innovation Institute, BioMedDI. In this role, he represents the government in a public-private partnership to address the spectrum of manufacturing challenges associated with biomanufacturing of non-medical products. He also serves as Science Director for Synthetic biology at the U.S. Office of Naval Research Global in London, United Kingdom. In his position, Dr. Rose is responsible for maintaining a global network throughout the synthetic biology community and provides general technology awareness to the US Navy.

**Sarah Sewall, PhD** is the Executive Vice President for Policy at In-Q-Tel. From 2014-2017, she served as Under Secretary of State for Civilian Security, Democracy and Human Rights. During the Clinton Administration, she served as the inaugural Deputy Assistant Secretary of Defense for Peacekeeping. Dr. Sewall taught at Harvard for over a decade, where she directed the Carr Center for Human Rights Policy and worked closely with the U.S. military to advance civilian protection in war.

**All Rights Reserved, In-Q-Tel, 2021**

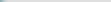
**Inder Singh** is the founder and CEO of Kinsa. With a network of 2.5M households, 5% of US elementary schools, and numerous enterprises that use Kinsa's illness insights tools, Kinsa helps families, communities and the system predict, prepare for, and prevent the spread of infectious illness. Kinsa built its early warning system for spreading infectious illness from the bottoms up: by first re-imagining the thermometer into a two-way communication channel to the newly sick and leveraging it to collect the "missing ingredient" data—for example, real-time symptom onset, and intra-family transmission rates—and delivering outbreak insights back to these families, school communities and enterprises. Prior to founding Kinsa, Inder served as the Executive Vice President of the Clinton Health Access Initiative. He holds 3 graduate degrees from Harvard and MIT and is a proud University of Michigan alum.

**Alexander Titus Ph.D.** is currently the Head of Public Sector Healthcare and Life Sciences Strategy at Google Cloud as well as an Adjunct Assistant Professor of Biotechnology at the University of New Hampshire and the founder of Bioeconomy.XYZ. Prior to Google, Titus was the head of biotechnology strategy at the Department of Defense, leading the team developing the modernization roadmap for the department. Titus is also a genomic data scientist by training with a PhD in Quantitative Biomedical Sciences from Dartmouth College and a BS and BA in biochemistry and biology (respectively) from the University of Puget Sound.

**Raffaela Wakeman** is the Director of Policy at In-Q-Tel. She previously served as Staff Director for the Strategic Technologies and Advanced Research Subcommittee of the House Permanent Select Committee on Intelligence and has experience at the Department of Defense, Department of Justice, Department of Treasury, and The Brookings Institution. She holds a JD from Georgetown University Law Center and an MS and BS in Political Science from MIT.

**Chenny Zhang** is an Associate on IQT's Investment Team. She previously worked as a Program Manager at In-Q-Tel, for the Defense Innovation Board, and as a Program Manager for Cisco. She holds an MA in International Economics and China Studies from Johns Hopkins University and a BA from Boston College.

**John Zicker** is Data Science Vice President at Kinsa. He was previously Chief Data Scientist and co-Founder, CEO at Amplion, COO at Vree Health, and has experience as a founder and leader of multiple start-ups. He holds a MSEE in Biomedical Engineering from the University of Wisconsin-Madison and a BSEE from the University of California-Davis.



15 Representing DARPA in that round table was Matt Hepburn, project offer for DARPA's Adept/Pandemic Prevention Platform [P3], & Fellow at Georgetown's Center for health security. He's behind the 60 day vaccine initiative for DARPA & Disease X.

## Col. Matthew Hepburn, M.D.

### Center Affiliate

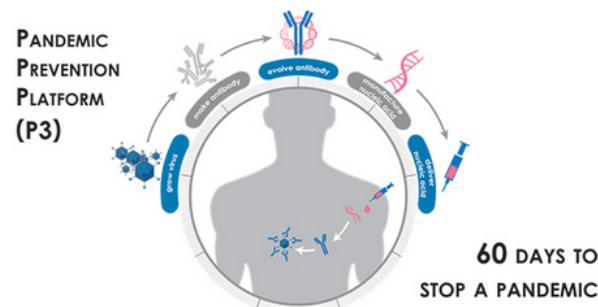
Col. Matthew Hepburn, M.D., is currently assigned to DARPA as a program manager, since 2013. Prior to joining DARPA, Col. Hepburn served as the Director of Medical Preparedness on the White House National Security Staff. Additional previous assignments include: Chief Medical Officer at a Level II medical facility in Iraq, clinical research director at the US Army Medical Research Institute for Infectious Diseases, exchange officer to the United Kingdom and internal medicine chief of residents at Brooke Army Medical Center at Fort Sam Houston, Texas.

Col. Hepburn completed internal medicine residency and infectious diseases fellowship programs at Brooke Army Medical Center. He holds Doctor of Medicine and Bachelor of Science in biomedical engineering degrees from Duke University.

## Removing the Viral Threat: Two Months to Stop Pandemic X from Taking Hold

*DARPA aims to develop an integrated end-to-end platform that uses nucleic acid sequences to halt the spread of viral infections in sixty days or less*

OUTREACH@DARPA.MIL  
2/6/2017



Over the past several years, [DARPA-funded researchers have pioneered RNA vaccine technology](#), a medical countermeasure against infectious diseases that uses coded genetic constructs to stimulate production of viral proteins in the body, which in turn can trigger a protective antibody response. As a follow-on effort, DARPA funded research into genetic constructs that can directly stimulate production of antibodies in the body.<sup>1,2</sup> DARPA is now launching the Pandemic Prevention Platform (P3) program, aimed at developing that foundational work into an entire system capable of halting the spread of any viral disease outbreak before it can escalate to pandemic status. Such a capability would offer a stark contrast to the state of the art for developing and deploying traditional vaccines—a process that does not deliver treatments to patients until months, years, or even decades after a viral threat emerges.

"DARPA's goal is to create a technology platform that can place a protective treatment into health providers' hands within 60 days of a pathogen being identified, and have that treatment induce protection in patients within three days of administration. We need to be able to move at this speed considering how quickly outbreaks can get out of control," [said Matt Hepburn, the P3 Program Manager](#). "The technology needs to work on any viral disease, whether it's one humans have faced before or not."

[Recent outbreaks of viral infectious diseases such as Zika, H1N1 influenza, and Ebola have cast into sharp relief the inability of the global health system to rapidly contain the spread of a disease using existing tools and procedures. State-of-the-art medical countermeasures typically take many months or even years to develop, produce, distribute, and administer. These solutions often](#)

16  Lastly, JHCHS in April of 2020 at the start of the Pandemic wrote a proposal to Congress urging congress for "A new dedicated Virus 201 strategy, program, & funding must be created to achieve this goal

through HHS's BARDA, the DODs Joint Program Executive Office for Chemical and Biological Defense (JPEO), In-Q-Tel & DARPA"

The Virus 201 Medical Countermeasure Strategy should be coordinated through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by HHS ASPR and DOD JPEO, with each agency supporting product candidates that best meet the needs of the populations they serve. PHEMCE must ensure collaboration with DARPA and In-Q-Tel.

### **VIRUS 201 MEDICAL COUNTERMEASURES STRATEGY**

Virus 201 means a previously unidentified viral threat, whether naturally occurring or man-made. These pathogens can affect both military personnel and the American public. DOD and HHS investment strategies should be coordinated through PHEMCE, with DOD taking the lead on products targeted to protect young, healthy military personnel, and HHS leading on other products needed to protect the diverse American public, including children and other vulnerable populations.

Since Virus 201 medical countermeasures may not have a commercial market that drives private sector investment, it is essential that a sustainable public-private partnership model and dedicated funding be created to share the development risk, incentivize development of new medical countermeasures, and invest in faster capabilities to respond to potential pandemics. Such countermeasures may include:

- **Antivirals:** In the time before a vaccine is available, antiviral treatments must be developed and deployed to decrease complications, hospitalizations, contagiousness, and mortality. Novel antiviral therapies range from small molecules to monoclonal antibody-based products. Under this proposed Virus 201 Medical Countermeasure Strategy, several kinds of antiviral therapies should simultaneously be supported.
- **Vaccines:** Vaccines are the best solution to protecting Americans from novel viruses, but they usually take the longest to develop. Vaccine technologies have progressed in recent years to include several promising platform technologies that can be more quickly leveraged once a threat has been characterized. More can be done to develop better and faster vaccine platform technologies as well as next-generation manufacturing capabilities that enable faster response.

### **COVID-19 Proposal:**

#### **FUNDING FOR NEW INITIATIVES AT HHS AND DOD TO RAPIDLY DEVELOP MEDICAL COUNTERMEASURES FOR NOVEL INFECTIOUS DISEASES IN MONTHS, NOT YEARS**

##### **PROBLEM**

Today's COVID-19 pandemic is an undeniable example of an increasing global trend of deadly infectious disease outbreaks. More than 200,000 people are dead, communities are shut down, and huge economic losses are occurring around the world. The profound effects of this pandemic must galvanize the US government to do everything in its power to prevent this from happening again. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner.

Our best defense is safe and effective medical countermeasures: drugs, vaccines, and diagnostics. However, the development of these life-saving products still takes years.

When the next deadly pathogen emerges, the United States needs to move much faster to develop and deploy medical countermeasures. Existing programs at HHS and DOD are primarily directed toward specific known, high-priority health security threats (including chemical, biological, radiological, and nuclear threats, and pandemic influenza). There is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats, referred to here as Virus 201.

##### **PROPOSAL**

The United States must set an ambitious goal of rapidly developing medical countermeasures for novel or unknown threats in months, not years. Innovative technologies, outside-the-box thinking, and game-changing science must be harnessed to meet this goal.

A new dedicated Virus 201 strategy, program, and funding must be created to achieve this goal

April 30, 2020 – Today's COVID-19 pandemic is an undeniable example of an increasing global trend of deadly infectious disease outbreaks. More than 200,000 people are dead, communities are shut down, and huge economic losses are occurring around the world. The profound effects of this pandemic must galvanize the US government to do everything in its power to prevent this from happening again. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner.

Our best defense is safe and effective medical countermeasures: drugs, vaccines, and diagnostics. However, the development of these life-saving products still takes years.

The United States must set an ambitious goal of rapidly developing medical countermeasures for novel or unknown threats in months, not years. Innovative technologies, outside-the-box thinking, and game-changing science must be harnessed to meet this goal.

The Center for Health Security calls for a new dedicated Virus 201 strategy and program, and funding must be created to achieve this goal through the HHS Biomedical Advanced Research and Development Authority (BARDA) and the DOD Joint Program Executive Office for Chemical and Biological Defense (JPEO). This strategy should not compete with or cannibalize other important medical countermeasure development efforts focused on specific known threats, and it should involve other innovative agencies like DARPA and In-Q-Tel.

Therefore, a new congressional appropriation of \$1 billion, divided equally between HHS and DOD, should be provided to enable these agencies to initiate a robust and coordinated strategy to accomplish this goal before the next virus threatens the globe.

HOME &gt;

JOHNS HOPKINS CENTER FOR HEALTH SECURITY CALLS FOR FUNDING FOR NEW INITIATIVES TO RAPIDLY DEVELOP MEDICAL COUNTERMEASURES FOR NOVEL INFECTIOUS DISEASES IN MONTHS, NOT YEARS



# Johns Hopkins Center for Health Security Calls for Funding for New Initiatives to Rapidly Develop Medical Countermeasures for Novel Infectious Diseases in Months, Not Years

## CENTER NEWS

Published **April 30, 2020**

17  Those are either some FANTASTIC coincidences or some serious RICO case evidence against these aforementioned entities for their obvious involvement as an undefined criminal organization. Links for ALL will be in the comments. Thank you for reading! 

Wait, I forgot to tell you. In 2017, when Metabiota and EcoHealth Alliance [EHA] were being Shuffled around China by USAID, Kevin Olival of EHA worked with In-Q-Tel on another vaccine/disease testing roundtable. 

4. Regulatory issues remain, and behind them lurk all of the business hurdles inherent to new diagnostic technologies: low return on investment, uncertain reimbursement structures, and the need to educate users (from clinical labs to the bedside) in their operation and the interpretation of sequence data. Public health could leverage a data stream from in-clinic use of portable sequencers, but getting portable DNA sequencing into the clinical setting will require its approval as a diagnostic technology. The regulatory environment is slowly evolving to cover this technology; a recent example (Dec 2016) of a next generation sequencing test receiving FDA approval for use as a companion diagnostic is FoundationFocus™ CDx<sub>BRCA</sub> from Foundation Medicine for the qualitative detection of *BRCA 1/2* alterations for ovarian cancer therapeutics<sup>1</sup> and the recently approved Oncomine Dx Target Test from Thermo Fisher<sup>2</sup>.
5. The exploitation of portable sequencing in the field during epidemics urgently requires new tools for collaboration among operators at widely dispersed locations. One example of such a tool is Nextstrain ([nextstrain.org](http://nextstrain.org)), which is an effort to create a portal that can allow scientists to analyze and dynamically visualize new data as they are received from

<sup>1</sup> <http://investors.foundationmedicine.com/releasedetail.cfm?ReleaseID=1004896>

<sup>2</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160045>



fielded DNA sequencers. Such portals should also facilitate the distribution of updated information based on near-real-time genome evolution tracking.

The Roundtable included experts from industry, academia, finance and several USG agencies who manufacture, consume, invest in, or develop use cases for sequencing applications as they relate to disease outbreaks. The discussion took place over a single day, included invited presentations from four participants plus prepared remarks from three others (see below), and was held on a not-for-attribution basis. (The participants agreed to allow IQT to publish a summary of key insights from the meeting. In addition, participants named below consented to allow us to use their names in this report.)

### Summary of Discussion

The discussion at this round table was organized to discuss three questions:

1. What might be specific applications of portable sequencers for infectious disease detection and management? This discussion was opened with presentations on potential use cases from Kevin Olival of the Eco-Health Alliance (on pathogen discovery prior to outbreaks), Trevor Bedford of the Fred Hutchinson Cancer Center (on sequencing during outbreaks to track the origin and evolution of pathogens during outbreaks), and Alan Rudolph of Colorado State University (on sequencing applications in food safety, agriculture and soil quality).

© 2017 In-Q-Tel, Inc.



Portable Sequencing Roundtable Summary

2. What operational characteristics, performance metrics, and supporting technology or infrastructure will make portable sequencers more applicable to the problem? This discussion began with an in-depth briefing from James Brayer of Oxford Nanopore (on the current capabilities of the MinION sequencer), and from Sterling Thomas of Noblis, Inc (on bioinformatics-related challenges to fieldable sequencing).

2. What operational characteristics, performance metrics, and supporting technology or infrastructure will make portable sequencers more applicable to the problem? This discussion began with an in-depth briefing from James Brayer of Oxford Nanopore (on the current capabilities of the MinION sequencer), and from Sterling Thomas of Noblis, Inc (on bioinformatics-related challenges to fieldable sequencing).
3. What are the market drivers and opportunities? Alex de Winter of GE Ventures and Mickey Urdea of Halteres Associates opened this section with discussions of the investment challenges associated with diagnostics technologies.

#### Discussion Topics

Several key take-away messages emerged from the discussion:

- 1) **The technology.** Portable sequencing is here. The quality and quantity of data generated by MinION are substantially improved over just a year ago, and will continue to improve. Oxford Nanopore has a tremendous first-to-market advantage, but we know of and expect other vendors to enter the market. James Brayer of Oxford Nanopore gave an update on the current specifications of MinION sequencers. The devices have seen a significant jump in the accuracy in base-calling, which is now in the low 90%’s. This is still lower than the 99+% of Illumina systems, but the quality of sequence is ramping quickly, and attendees noted that there is value to being able to quickly sequence a sample on-site and transmit data, rather than transport a sample. MinION is beginning to realize that potential.
- 2) **The importance of accuracy and sensitivity.** The sequencing accuracy issue is part of a larger conversation on the problem of false positive and false negative results. Other contributors to false positive results include the incompleteness of reference data for comparative purposes and the presence of microorganisms that are “conditional” or “opportunistic” pathogens (e.g. *Staphylococcus aureus*, *Clostridium difficile*), meaning they may be present without causing a disease, but may become pathogenic upon a change in conditions (e.g. immune status, nutritional state). A false negative result may occur due to the throughput of the sequencer when processing samples in which the pathogen’s genome is a small fraction of the total DNA or RNA in a sample. For example, in a clinical sample, the vast majority of DNA molecules will be host DNA. Sequencing the pathogen will therefore require sequencing a large excess of host DNA molecules to accumulate enough pathogen sequence to assemble a genome, unless techniques are employed prior to sequencing to enrich the pathogen-specific nucleic acids. Another contributor to false negative results is the characteristic of some pathogens residing in anatomically inaccessible reservoirs, such as cryptosporidium that burrow into the intestinal wall. Sensitivity and accuracy thresholds,



## Roundtable Discussion on Portable Sequencing for Infectious Disease Detection, Diagnosis, Discrimination, and Discovery

**Background** - This paper reports on a February 28, 2017 Roundtable Discussion convened by b.Next, an IQT Lab.

Several companies are developing DNA sequencing devices that can enable users to sequence DNA outside the traditional laboratory setting. Among them, Oxford Nanopore is perhaps the most well-known. The advent of portable sequencing devices opens up a wide variety of potential use cases that range from point-of-care medical diagnostics to on-site agricultural pest analysis. It will soon be common for scientists to study animal and plant genetics and the structure of microbial communities close to where these species are found in nature. In the realm of managing epidemics, the current state of portable sequencing technology presents potential opportunities to accelerate the collection of pathogen genomic sequence data during an outbreak. Distributed sufficiently broadly, portable sequencers could function as "sensors" that help detect the spread and evolution of a pathogen.

**Purpose** - To explore this concept further, IQT hosted a one-day discussion on this topic, with the goal of learning at what stages in the development of an epidemic (see the illustration at <https://www.bnxt.org/premise/>) portable sequencing may have the greatest immediate and longer-term impact on quenching an outbreak.

The Roundtable included experts from industry, academia, finance and several USG agencies who manufacture, consume, invest in, or develop use cases for sequencing applications as they relate to disease outbreaks. The discussion took place over a single day, included invited presentations from four participants plus prepared remarks from three others (see below), and was held on a not-for-attribution basis. (The participants agreed to allow IQT to publish a summary of key insights from the meeting. In addition, participants named below consented to allow us to use their names in this report.)

### Summary of Discussion

The discussion at this round table was organized to discuss three questions:

1. What might be specific applications of portable sequencers for infectious disease detection and management? This discussion was opened with presentations on potential use cases from Kevin Olival of the Eco-Health Alliance (on pathogen discovery prior to outbreaks), Trevor Bedford of the Fred Hutchinson Cancer Center (on sequencing during outbreaks to track the origin and evolution of pathogens during outbreaks), and Alan Rudolph of Colorado State University (on sequencing applications in food safety, agriculture and soil quality).

© 2017 In-Q-Tel, Inc.

### SOURCES:

Darby^

INQTEL^

Aug 22, 2023

In-Q-Tel, 2021

IQT Roundtable: Capabilities Required for Pandemic Response – August 2021

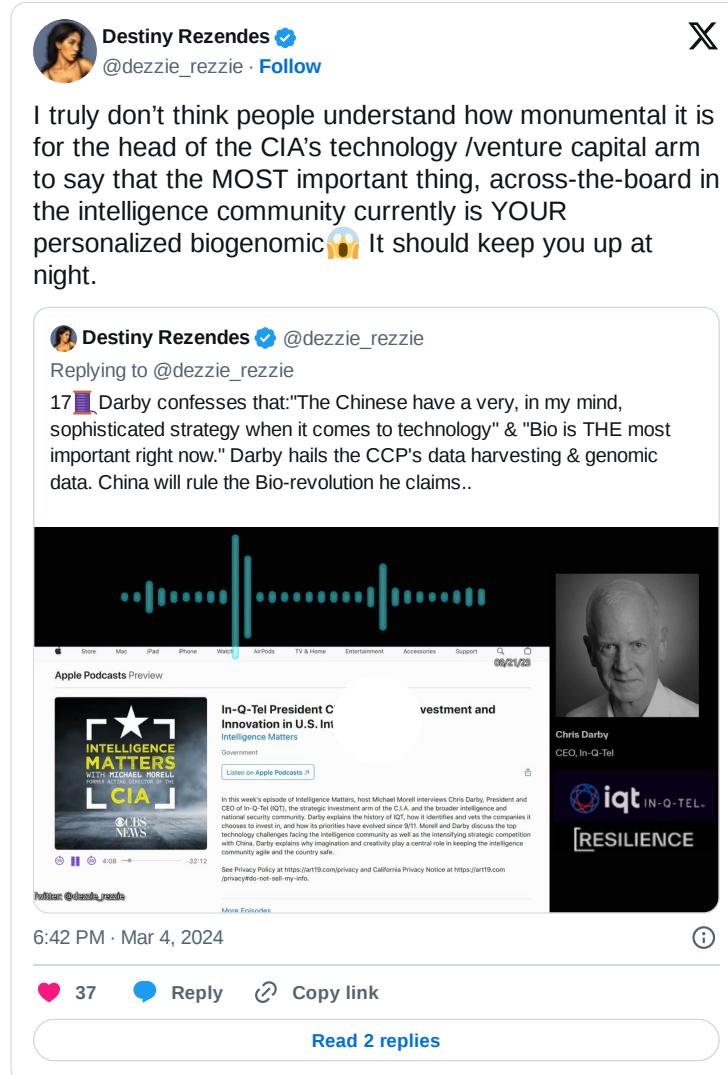
## ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

December 2019:

IQT Nanopore+EHA Kevin Olival Feb 2017 roundtable:

Roundtable Discussion on Portable Sequencing for Infectious Disease Detection, Diagnosis, Discrimination, and Discovery

Background - This paper reports on a February 28, 2017 Roundtable Discussion convened by , an IQT Lab:



Destiny Rezendes  @dezzie\_rezzie · Follow

I truly don't think people understand how monumental it is for the head of the CIA's technology /venture capital arm to say that the MOST important thing, across-the-board in the intelligence community currently is YOUR personalized biogenomic  It should keep you up at night.

Destiny Rezendes  @dezzie\_rezzie

Replies to @dezzie\_rezzie

17  Darby confesses that:"The Chinese have a very, in my mind, sophisticated strategy when it comes to technology" & "Bio is THE most important right now." Darby hails the CCP's data harvesting & genomic data. China will rule the Bio-revolution he claims..

Apple Podcasts Preview

In-Q-Tel President C Innovation in U.S. Int Intelligence Matters

Chris Darby

CEO, In-Q-Tel

iqt IN-Q-TEL

RESILIENCE

6:42 PM · Mar 4, 2024

37 ·   

Read 2 replies



Destiny Rezendes

@dezzie\_rezzie · [Follow](#)



Replying to @dezzie\_rezzie

2 The report was written in Dec.2019 by the CIA's venture capital arm, In-Q-Tel & was a summary of their round-table meeting held Dec 5th 2019 titled; LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS



ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING  
LARGE-SCALE EPIDEMICS

December 2019

#### Introduction

The capabilities required to manage a large-scale epidemic are multifaceted, complex and range across a number of critical domains – the ability to detect and recognize the presence of disease in the community; the capacity to design, manufacture and deliver life-saving medical countermeasures, including therapeutics and vaccine; and the process by which healthcare services can be delivered to the population-in-need in a scalable fashion that maintains the highest possible standard of care.

#### Background

In-Q-Tel/B.Next convened a Roundtable meeting, held on December 5, 2019 in Arlington, VA to explore the role digital health technologies can play to support the response to large infectious disease outbreaks. Roundtable participants included experts drawn from several United States (U.S.) Government agencies, academia, private-sector technology companies and members of the In-Q-Tel and B.Next team. The discussion took place over a single day. There were two invited presentations, and the meeting was conducted on a not-for-attribution basis.

This Roundtable discussion was the first of a series of meetings which intend to explore how digital health technologies might be applied to epidemic management. This meeting was focused expressly on two broad themes -- the role enabling technologies can play in allowing the population to initiate self-triage, and how such technologies might aid in preserving the integrity of hospital services over the course of an extended outbreak event. Subsequent Roundtable discussions in this series will explore the potential of these technological platforms to help provide appropriate medical treatment in an austere environment where resources are scarce. We will also examine how digital health technologies might enable the collection, analysis and coordination of data in order to provide essential situational awareness, thereby facilitating the creation of a "learning healthcare system" in the midst of an epidemic crisis.

8:43 PM · Aug 22, 2023



251 Reply Copy link

[Read 8 replies](#)

[https://www.gpmb.org/about-us#tab=tab\\_2](https://www.gpmb.org/about-us#tab=tab_2)



#### Intelligence report says US split on Covid-19 origins

A declassified report finds no direct evidence the virus came from a lab, but adds it can't be ruled out.

<https://www.bbc.com/news/world-us-canada-66005240>

[https://www.iqt.org/wp-content/uploads/2022/12/RT-FINAL-REPORT\\_09\\_18\\_21.pdf](https://www.iqt.org/wp-content/uploads/2022/12/RT-FINAL-REPORT_09_18_21.pdf)

<https://www.iqt.org/wp-content/uploads/2022/12/Digital-Health-Roundtable-Report.pdf>

[https://www.iqt.org/wp-content/uploads/2022/12/Portable-Seq-RT-summary\\_final.pdf](https://www.iqt.org/wp-content/uploads/2022/12/Portable-Seq-RT-summary_final.pdf)

<https://centerforhealthsecurity.org/2020/johns-hopkins-center-for-health-security-calls-for-funding-for-new-initiatives-to-rapidly-develop-medical-countermeasures-for-novel-infectious>

[https://www.iqt.org/wp-content/uploads/2022/12/drugdeliveryFindings\\_nov5.pdf](https://www.iqt.org/wp-content/uploads/2022/12/drugdeliveryFindings_nov5.pdf)

<https://centerforhealthsecurity.org/2020/johns-hopkins-center-for-health-security-calls-for-funding-for-new-initiatives-to-rapidly-develop-medical-countermeasures-for-novel-infectious>

[B.Next](#)

[https://www.iqt.org/wp-content/uploads/2022/12/Portable-Seq-RT-summary\\_final.pdf](https://www.iqt.org/wp-content/uploads/2022/12/Portable-Seq-RT-summary_final.pdf)

• • •